

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
19 April 2001 (19.04.2001)

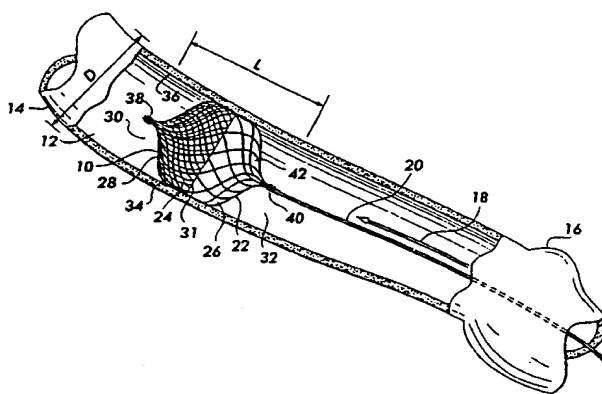
PCT

(10) International Publication Number  
**WO 01/26726 A1**

- (51) International Patent Classification<sup>7</sup>: A61M 29/00
- (21) International Application Number: PCT/US00/24572
- (22) International Filing Date:  
7 September 2000 (07.09.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
60/158,197 7 October 1999 (07.10.1999) US  
09/494,323 28 January 2000 (28.01.2000) US  
09/645,842 25 August 2000 (25.08.2000) US
- (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:  
US 09/645,842 (CIP)  
Filed on 25 August 2000 (25.08.2000)
- (71) Applicant (for all designated States except US): PRODESCO, INC. [US/US]; 700 Park Avenue, P.O. Box 237, Perkasi, PA 18944 (US).
- (72) Inventor; and  
(75) Inventor/Applicant (for US only): GREENHALGH, E., Skott [US/US]; 7943 Pleasant Avenue, Wyndmoor, PA 19038 (US).
- (74) Agents: BARRON, Alexis et al.; Synnestvedt & Lechner LLP, 2600 Aramark Tower, 1101 Market Street, Philadelphia, PA 19107-2950 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:  
— With international search report.

[Continued on next page]

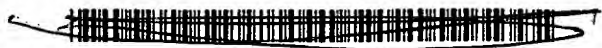
(54) Title: INTRALUMINAL FILTER



(57) Abstract: An intraluminal filter (10) is formed of a plurality of flexible, resilient monofilament wires (22) inter-braided in a relatively open mesh forming a basket (26) with a plurality of multi-filament yarns (24) braided in relatively closed mesh having a predetermined porosity forming a filter element (28). The filter element (28) is positioned distally of the basket forming a concave portion, the remaining portion of the basket being unobstructed, and forming openings facing the concave portion. The filter (10) is elastically deformable between two shape states, the first having a small diameter enabling the filter to slide within the bore (48) of a catheter (44) for positioning the filter (10) in the lumen of an artery, the second shape state having a substantially larger diameter sized to sealing inter-fit within the artery lumen. The filter (10) is biased, and will expand upon release from the catheter (44) to the second shape state. The open portion is positioned upstream allowing blood to flow into the concave portion of the filter element (28). A tether (20) is attached to the upstream end of the filter (10) allowing it to be withdrawn in the catheter bore (48) for removing the filter (10) from the artery.

WO 01/26726 A1

WO 01/26726 A1



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## INTRALUMINAL FILTER

### Related Applications

5 This application is based on and claims the benefit of prior filed co-pending U.S. Application No. 09/494,323, filed January 28, 2000, which is based upon and claims the benefit of prior filed co-pending Provisional Patent Application No. 60/158,197, filed October 7, 1999.

### Field of the Invention

10 This invention relates to a filter temporarily positionable in a lumen, for example, the lumen of an artery, for trapping and removing particles from a fluid flowing through the lumen while allowing the fluid to flow relatively unimpeded through it.

### 15 Background of the Invention

Various vascular procedures, such as the removal of a stenosis occluding an artery or the positioning of a stent graft to reinforce the weakened artery wall at an aneurysm, tend to dislodge particles or emboli from the wall of the  
20 artery. The dislodged emboli become entrained in the blood stream flowing through the lumen of the artery. If allowed to remain in the blood flow, the emboli are carried through

the vascular system until they lodge in a blood vessel thereby forming a blockage or embolism. Depending upon the size and/or volume of the emboli and where in the vascular system they lodge, the consequences of an embolism can be  
5 extremely serious, resulting, for example, in the sudden cessation of blood flow to an extremity, an organ, such as a kidney, the brain or the heart.

There is clearly a need for a filter which can be temporarily positioned in the lumen of an artery downstream  
10 from the point where a medical procedure is taking place which may dislodge emboli from the artery wall. The filter should trap emboli above a predetermined size but allow the blood to flow through relatively unimpeded. The filter should be removable from the artery after the procedure is  
15 complete and no further emboli are dislodged, the filter bringing all of the trapped emboli with it out of the vascular system.

#### Summary and Objects of the Invention

The invention concerns an intraluminal filter  
20 positionable within a lumen for separating entrained particles from a fluid flowing within the lumen. Although other applications are envisioned, the filter is particularly well suited for vascular use.

In its preferred embodiment, the intraluminal filter  
25 according to the invention comprises a plurality of filamentary members interlaced to form a basket. The basket has an upstream portion and a concave portion arranged to face the upstream portion. The upstream portion has openings sized to allow the fluid and the entrained particles to flow  
30 through and into said concave portion when the upstream portion is oriented upstream within the lumen. The concave portion comprises a filter element and has openings of predetermined size smaller than the first named openings. The openings of the concave portion are sized to capture the  
35 entrained particles while allowing the fluid to flow therethrough.

In a preferred embodiment for vascular use, the intraluminal filter also has a means for biasing the basket from a first shape state to a biased second shape state. The first shape state has a first diameter sized to allow the  
5 basket to slidably fit within the bore of a catheter positionable within said lumen. The biased second shape state has a second diameter substantially larger than the first diameter, the biased second shape state being sized to allow the basket to sealingly interfit within the lumen.

10 There are various biasing means contemplated. For example, the biasing means may comprise selected ones of the filamentary members. These selected filamentary members being resilient and biased by internal elastic forces to expand the basket into the biased second shape state when the  
15 basket is released from the catheter.

In addition to or instead of the selected filamentary members, the biasing means may comprise a plurality of supplemental filamentary members. The supplemental  
20 filamentary members are elastic and oriented to compress the basket into the biased second shape state. The supplemental filamentary members are under tension when the basket is in the first shape state and compress the basket to bias it into the second shape state upon release of the basket from the catheter.

25

Another alternate biasing means comprises an elongated elastic member having one end attached to the upstream portion and the other end attached to the concave portion of the basket. The elastic member is under tension when the  
30 basket is in the first shape state to bias the upstream portion toward the concave portion in order to expand the basket from the first to the second shape state.

Preferably, the filamentary members are interlaced by braiding, a method of interlacing which allows the basket to  
35 readily assume the first and second shape states. It is convenient to form the basket by braiding the filamentary

members into a tube having a predetermined length. The tube has oppositely arranged ends which are gathered and cinched to form the basket. Preferably, one of the ends forms the second portion of the basket which is not obstructed by the  
5 second filamentary members, thus, forming the openings at that end.

In an alternate embodiment, the filter includes a plurality of projections extending angularly outwardly from the filter. The projections are interengagable with the  
10 internal surface of the lumen and prevent downstream movement of the filter. The projections are arranged to point in the downstream direction to allow them to readily disengage from the lumen when the filter is moved in an upstream direction for retraction of the filter into the catheter.

15 The projections can be conveniently formed by cutting some of the selected filamentary members forming the basket at points adjacent to the concave portion of the basket. The projections adjacent to the first portion of the basket are relatively unrestrained and project angularly outwardly.  
20 The complementary end portions at the concave portion of the basket which result from the cut filamentary members are restrained by filamentary members forming the filter element and, thus, do not tend to extend outwardly from the filter. Preferably, the cut filamentary members forming the  
25 projections are present in a one to one ratio with the uncut filamentary members forming the basket.

It is advantageous to attach a flexible tether to the unobstructed end of the basket. The tether has a predetermined length and is extendable through the catheter  
30 for allowing the intraluminal filter to be manually withdrawn from the lumen into a catheter bore, for example, after completion of a surgical procedure when the filter is no longer required. The filter, along with the captured emboli, are then removed from the lumen when the catheter is removed.

35 A preferred method of forming an intraluminal filter according to the invention comprises the steps of:

- (a) braiding a plurality of flexible, resilient  
filamentary members into a relatively open mesh forming an  
elastically deformable tube, the filamentary members  
providing a radial bias to the tube, urging the tube to  
5 assume a predetermined length and diameter;
- (b) interbraiding a multiplicity of yarns with the  
first filamentary members to form, with the filamentary  
members, a surface having a predetermined porosity, the  
surface comprising the filter element or means;
- 10 (c) gathering each end of the tube and cinching each  
end together to form an elastically deformable basket;
- (d) removing the yarns from a portion of the basket at  
one end of the tube, thereby forming openings at the one end  
which allow the fluid and particles to flow into the filter;
- 15 and
- (e) attaching the yarns to the first filamentary  
members adjacent to the unobstructed portion of the basket.

Although the steps of removing and attaching the yarns  
can be accomplished in any of several ways, it is preferred  
20 to use a laser to ablate the multifilament yarns from the  
portion of the basket which is to be unobstructed and use the  
same laser to heat seal the yarns to the filamentary members  
adjacent to the unobstructed portion of the basket. The  
laser allows for pinpoint accuracy in targeting the yarns to  
25 be removed and heat sealed.

It is an object of the invention to provide a filter  
positionable within the lumen of an artery.

It is another object of the invention to provide a  
filter having a filter element of braided filamentary members  
30 to capture emboli above a certain size entrained with the  
blood in the artery.

It is yet another object of the invention to provide a  
filter which is elastically collapsible into a first shape  
state having a diameter sized to permit the filter to



slidingly interfit within a catheter bore for positioning the filter within the artery lumen.

It is still another object of the invention to provide a filter which is self-expanding into a second shape state  
5 having a second diameter substantially larger than the diameter of the first shape state, the second diameter being sized to allow the filter to sealingly interfit within the artery lumen.

It is again another object of the invention to provide a  
10 filter which is collapsible from the second shape state to the first shape state by withdrawing the filter into the catheter bore for removing the filter from the artery lumen.

These and other objects will become apparent from a consideration of the following drawings and detailed  
15 description of the invention.

#### Brief Description of the Drawings

Figure 1 is a partial cross-sectional view of an intraluminal filter according to the invention positioned in an artery;

20 Figures 2a-2f are partial cross-sectional views depicting a sequence of steps for deploying and recovering an intraluminal filter to and from an artery as seen in Figure 1;

Figure 3 shows a partial cross-sectional view of an  
25 alternate embodiment of an intraluminal filter as shown in Figure 1;

Figure 4 shows a side view of an alternate embodiment of an intraluminal filter according to the invention;

Figure 5 shows a side view of another alternate  
30 embodiment of an intraluminal filter according to the invention;

Figure 6 shows a cross-sectional view of an alternate embodiment of an intraluminal filter according to the invention;

Figure 7 shows a side view of another alternate embodiment of an intraluminal filter according to the invention; and

Figure 8 shows a flow chart describing a method of making an intraluminal filter according to the invention.

#### Detailed Description of the Preferred Embodiment

10 The intraluminal filter for vascular use preferably comprises a flexible, resilient structure adapted to assume at least two different shape states, the first shape state being adapted to interfit slidably within the lumen of an insertion catheter, the second shape state being adapted to  
15 interfit within the lumen of a vascular vessel. The resilient structure further comprises a distally arranged filter element which sealingly engages the inside circumference of the vessel to trap and retain emboli flowing through the vessel, the emboli being removed from the  
20 vascular system upon withdrawal of the intraluminal filter.

Figure 1 shows an intraluminal filter 10 according to the invention, deployed within the lumen 12 of an artery 14. Filter 10 is shown downstream of an aneurysm 16 in the artery, the blood flow direction being indicated by arrow 18.  
25 Filter 10 is held on a tether 20 which leads to a catheter (not shown) allowing the filter to be retrieved from the lumen after a medical procedure repairing the aneurysm is completed.

Filter 10 comprises resilient monofilaments which  
30 preferably comprise braided wires 22. In the preferred embodiment, wires 22 are co-braided with other filamentary members preferably comprising polymer yarns 24. The wires 22 and yarns 24 are braided into a generally bulbous or spherical shape. Wires 22 are braided in a relatively open

mesh basket 26 and form a flexible structure supporting the polymer yarns which are braided to form a filter element 28 located distally and forming the downstream portion 30 of the filter 10. The wires 22 of the open mesh basket 26 are  
5 braided in a relatively open mesh and form an unobstructed upstream portion 32 of the filter to allow for unrestricted flow of blood or other fluid into the filter.

Wires 22 have diameters ranging from 5 to 500 microns. Nitinol, an alloy of nickel and titanium, is the preferred  
10 material for wires 22 because it is easily braided, biocompatible, radiopaque and highly elastic, having a yield strength on the order of 65,000 psi. Other metals such as stainless steel, titanium, elgiloy and alloys of gold, tantalum or platinum having significant flexibility,  
15 elasticity, resilience and stiffness can also be used to form the wires. Non-metals such as polymers can also be used, but are not preferred for vascular applications because the filaments are not radiopaque and require larger diameters to achieve the strength and stiffness needed, resulting in a  
20 generally bulkier filter.

The properties of the wires in conjunction with the braided structure allow the filter to deform elastically and radially contract from the bulbous form, shown in Figure 1, to the thin, elongated cylindrical shape, seen in Figure 2a.  
25 These wire and braid characteristics allow the filter 10, when in its cylindrical shape, to be inserted into the lumen of a catheter and then to expand radially to the bulbous shape of Figure 1 automatically when released from the catheter within the artery 14, as described in further detail  
30 below.

Filter element 28 (see Figure 1), located distally and forming the downstream portion 30 of the filter 10, is preferably a braided polymer textile formed from polyester yarns 24 in a densely braided mesh 34 co-braided with the  
35 metal wires 22. Polyester is the preferred material because it is a well understood biomedical material with a long and

successful implant history. Furthermore, polyester can be coated with bioactive chemicals, ablated or fused in a precisely controlled manner by heat, such as from a laser, which is useful for the manufacture of the filter as  
5 described below.

Other materials useful for forming the polymer yarns of the filter element 28 include ePTFE, PTFE, PET, nylon, polyethylene, PGA and PLA. The yarn material is chosen for its compatibility with human tissue, as well as mechanical  
10 properties, such as elongation, strength, flexibility and toughness.

Yarns 24 range in diameter from 5 microns to 500 microns (5 to 100 denier). Multifilament yarns are preferred, but other types of yarns such as monofilament yarns, textured or  
15 flat yarns and yarns formed from slit film can also be used.

While a textile filter element is preferred, other filter means are also feasible, such as solid films with holes formed by chemical means, laser or mechanical penetration, to achieve the desired porosity.

20 The diameter of the polymer yarns 24 and the mesh density are controlled to yield a filter element 28 preferably having a porosity ranging between 60% and 90%. The porosity is quantified by the ratio of the area of openings in the fabric to the total fabric area, multiplied  
25 by 100. Mesh in this porosity range will capture emboli in the bloodstream yet allow blood to flow substantially unimpeded, thus, allowing the filter 10 to remain in place for relatively long durations without occluding the artery 14. This enables the filter to be used in lengthy medical  
30 procedures.

Intraluminal filters 10 according to the invention are preferably formed by co-braiding metal wires 22 and polymer yarns 24 together on a braiding machine into a continuous tube or sleeve. The differing mesh densities for the wires

and the polymer yarns are effected by the ratio of carriers on the braiding machine having wire versus the carriers having polymer yarns. For example, to create the dense mesh 34 of polymer yarns 24 required for the filter element 28, 5 between 24 and 196 carriers will feed polymer to the braiding machine, whereas the open mesh basket 26 of wires 22 requires between 24 and 48 carriers feeding wire to the braiding machine. A preferred braiding set up features 72 filaments of 40 denier polyester yarn, 12 filaments of 0.005 inch 10 diameter nitinol wires interbraided over a 6mm mandrel at a braid angle of 37°. This configuration achieves a porosity of 80%. In an alternate embodiment, 132 filaments of 20 denier polyester yarn are interbraided with 12 filaments of 0.005 inch diameter nitinol wires over a 6mm mandrel at a 15 braid angle of 37°, achieving a porosity of 78%. The porosity of the filter element is readily controlled by varying the denier of the yarn and the mesh density. These parameters also affect the relative flexibility of the filter element, with higher mesh densities yielding stiffer filters.

20 The braiding machine forms a continuous tube of co-braided metal wires and polymer yarns having an unstressed diameter "D" (see Figure 1) which is tailored to be slightly larger than the particular lumen in which it will be used. A larger diameter tube ensures that the filter will be slightly 25 compressed by the inner wall 36 of lumen 12 and have an interference fit within the lumen. Friction between the filter 10 and inner wall fixes the position of the filter when it is deployed within the lumen.

In an alternate embodiment of the intraluminal filter, 30 shown in Figure 3, a plurality of the flexible wires 22 are cut at points 50 adjacent to the downstream portion of the basket 34 having the filter element 28. Cutting certain of the wires forms projections, in the form of the cut wire end portions 52, which extend angularly outwardly from the filter 35 and point in the down stream direction. The end portions 52 engage the lumen inner wall 36 and prevent downstream motion of the filter. The cut wires are relatively unrestrained by

the open mesh of the upstream portion 32 of the basket 26, allowing the end portions 52 to project outwardly. The complementary cut ends 54 residing on the downstream portion 30 of the filter are restrained by the filter element 28 and do not project outwardly. Because the end portions 52 point downstream, they prevent downstream motion of the filter but do not hinder upstream filter motion. The end portions readily disengage from the lumen when the filter is moved upstream, as, for example, when the filter is being withdrawn from the lumen into the catheter for removal of the filter from the vascular system. Furthermore, because the cut wires are interbraided with uncut wires the end portions 52 as well as the complementary cut ends 54 retract readily into the smaller diameter cylindrical shape, allowing the filter 10 to be retracted back into the catheter as described below. In this embodiment, it is preferred to interbraid 24 wires to form the basket 26 and cut every other wire, spacing the 12 cut wires at 30° intervals circumferentially around the filter and achieving a ratio of cut to uncut wires of one to one.

To form a filter 10, the continuous, co-braided tube is cut into discrete lengths "L" and cinched or crimped at each end by cinches 38 and 40. The length imparts stability to the filter against slippage and rotation when deployed in the lumen, and lengths on the order of 1.1 to 1.5 times the diameter of the lumen inner diameter are preferred for vascular use, for example. It is preferred to use a radiopaque, ductile material, such as platinum or stainless steel, to form cinches 38 and 40. Radiopaque material allows the filter to be detected via X-rays or fluroscopy to accurately determine its position.

Cinching the ends distorts the tube into the bulbous shape seen in Figure 1. Polymer yarns initially extend in a dense mesh over the entire surface of the bulbous shape, and these yarns must be removed from the upstream portion 32 to expose the open mesh basket 26 of wires 22 and form the entrance openings 42 allowing blood or other fluid to flow

into the filter. It is preferred to use a laser to ablate the polymer yarns off of the upstream portion, although other ablation methods, including chemical and mechanical methods, are feasible. The laser also fuses or heat seals the remaining polymer yarns 24 together and to the wires 22 at the boundary 31 between the upstream and downstream portions of the filter. The upstream cinch 40 forms a convenient point for attaching tether 20. Figure 8 presents a flow chart which depicts the steps for forming a filter according to the invention.

Because filter 10 has a support structure of resilient, flexible wires 22 braided in an open mesh basket 26 it is possible to distort the filter from its nominal or unstressed bulbous shape into an elongated cylindrical shape, seen in Figure 2a, by applying a tensile force to cinches 38 and 40. It is well known that braided structures exhibit a "trellis effect" wherein the braided wires rotate and slide relatively to one another when a force is applied. For the bulbous structure of the filter, this effect results in radial contraction of the filter with axial expansion and radial expansion upon axial contraction.

When the aforementioned tensile force is removed, the braid springs back into its nominal or unstressed shape due to elastic forces generated within the wires in response to the distortion. The wires themselves provide the means for biasing the filter into the expanded, bulbous shape. The degree of distortion per unit force applied is proportional to the mesh density with less dense meshes allowing for proportionally greater distortion from the nominal shape and higher associated elastic spring back forces.

Figure 4 illustrates an alternate means for biasing filter 10 into the second shape state using supplemental filamentary members 56 (shown in dashed line for clarity) which are elastic and under tension when the filter is in the first shape state. Supplemental filamentary members 56 extend between the upstream end 32 and downstream end 30 of

the filter and are thus oriented to compress the basket 26 into the second shape state upon release from the catheter. Preferably, the filter is formed by braiding the filamentary members such as wires 22 and yarns 24, and the supplemental  
5 filamentary members 56 are interbraided with the other filamentary members to take maximum advantage of the "trellis effect" enabling the members 56 to compress the filter and force it into the second shape state.

Another embodiment for biasing Filter 10 is shown in  
10 Figure 5 and features an elongated elastic element 58 having one end attached to the upstream portion 32 of the filter and the other end attached to the downstream or concave portion 30. The elastic member 58 is under tension when the basket 26 is in the first shape state and, thus, biases the filter  
15 into the second shape state by biasing the upstream portion 32 toward the downstream portion 30. The elastic member 58 shown comprises a coil spring, but other configuration, such as elastic filaments or an elastic tube, are also feasible.

Forming elastic element 58 from an elastic tube provides  
20 additional advantages as shown in the embodiment of Figure 6, wherein filter 10, shown positioned in artery 14, comprises an elastic tube 60 joining the upstream and downstream ends 32 and 30. Tube 60 allows the tether 20 to be decoupled from the filter and move independently of it. The tether can then  
25 be used as a guide wire which is easily snaked through arteries to provide a path for the catheter to follow. The tube 60 keeps the filter 10 coaxial with the tether 20 which prevents the filter from rotating upon deployment from the catheter thus ensuring proper positioning of the filter in  
30 the artery 14 with the upstream end 32 pointing upstream.

Tether 20, when functioning as a guide wire, passes through an aperture 62 defined by the tube 60 in the upstream end of the filter, passes through the tube and out of the filter through another aperture 64 defined by the tube in the  
35 downstream end of the filter. A stopper 66 is fixedly positioned on the tether 20 to ensure that the filter does



not disengage from the tether and possibly become lost in the artery. A surface 68, preferably positioned in the tube 60 at the upstream end 32 of the filter is engageable with the stopper to prevent disengagement and assist in recovery of  
5 the filter into the catheter after the operation is completed. Positioning surface 68 at the upstream end ensures that the filter will properly collapse into its thin elongate form and lessens the chances that the filter will be turned inside out when it is drawn back into the catheter.

10 Tube 60 also acts as a means for sealing aperture 64 and isolating it from the rest of the filter. Aperture 64 is positioned in the concave portion which comprises the filter element 28. If the tube did not seal the aperture, then emboli entering the filter through openings 42 in the  
15 upstream end of the filter would exit the filter through aperture 64 and not be trapped in the filter element 28.

In an alternate embodiment shown in Figure 7, a check valve 70 is used to seal the aperture 64 and prevent emboli from exiting the filter. Check valve 70 has a flexible flap  
20 72 on the inside of the filter element overlying opening 64, the flap normally being held in the closed position by the fluid pressure within the artery. When tether 20 is drawn toward the upstream end of the filter, stopper 66 engages the flap which, being flexible, moves inwardly to an open  
25 position allowing the stopper to pass through aperture 64 and eventually engage surface 68 formed at the upstream end 32 by the cinch 38. Fluid pressure within the artery then forces the flap 72 back into the closed position overlying and sealing aperture 64.

30 The properties of braided structures are used to great advantage in the filter 10 according to the invention, as shown in the sequence of Figures 2a-2f, which illustrates the use of the filter to capture emboli dislodged while installing a stent graft to repair an aneurysm.

35 Figure 2a depicts an artery 14 having an aneurysm 16. A catheter 44 containing filter 10 and a stent graft 46 is

positioned with its tip 44a downstream of aneurysm 16 as indicated by arrow 18 showing the direction of blood flow. Filter 10 is nearer the tip 44a of the catheter as it will be deployed first. While within catheter 44, filter 10 is  
5 maintained in its distorted cylindrical shape by the restraint of the catheter wall, thus, the filter is able to slide along the catheter through lumen 48.

Figure 2b shows filter 10 being pushed out from the tip 44a at the downstream location. As the filter emerges from  
10 the catheter 44, it is no longer restrained and springs open automatically by virtue of the elastic forces within the resilient wires 22. The filter tries to assume its stress free shape but encounters inner wall 36 of artery 14. The filter lodges against the inner wall 36 and friction between  
15 the filter and inner wall hold the filter in position despite the blood pressure which would otherwise tend to move the filter further downstream. Additionally or alternately, projections 52, when present, extend outwardly and engage the inner wall 36 (see Figure 3) to prevent downstream motion of  
20 the filter.

Figure 2c shows filter 10 fully deployed from the catheter in the proper orientation with the unobstructed upstream portion 32 of the open mesh basket 26 facing upstream and the dense mesh filter element 28 forming a  
25 concavity facing the blood flow 18. The porosity of the filter element 28 allows blood to flow without significant resistance. Catheter tip 44a is positioned at the downstream end 16a of aneurysm 16 in preparation to deploy the stent graft 46 to repair the aneurysm.

30 In Figure 2d, the stent graft is shown partially deployed within artery lumen 12 and attaching itself to the inner wall 36 of artery 14. This procedure dislodges emboli 50 from the artery inner wall. The emboli become entrained with the blood and flow downstream, through the unobstructed  
35 upstream portion 32 of the open mesh basket 26 and into filter 10 where the emboli become entrapped against the dense

mesh 34 of polymer yarns 24 forming the filter element 28 on the downstream portion 30 of the filter.

Figure 2e shows the stent graft 46 fully deployed and installed at aneurysm 16, the repair procedure being complete  
5 and no further emboli being dislodged from the artery.

Figure 2f shows filter 10 being recovered from artery 14. Recovery is effected by moving catheter tip 44a downstream into contact with upstream portion 32 of filter 10. Tension is applied to tether 20 to hold the filter in  
10 place as the catheter is pushed against the filter. Again, the flexible properties of the braided structure are manifest as filter 10 radially collapses as it is drawn into the catheter lumen 48 by the dual opposing action of the catheter and the tether. Blood in the filter flows out through filter  
15 element 28, but emboli 50 remain trapped within the filter and are removed from the artery once the filter is fully within the catheter and the catheter is removed from the artery.

Use of the intraluminal filter according to the  
20 invention will improve the success rate of vascular procedures by preventing complications due to embolisms caused by emboli dislodged during the procedure. Although the preferred field of application of the filter is for vascular applications, it can be employed in many procedures  
25 requiring that a temporary filter be deployed to collect, trap and separate particles from a fluid stream within a lumen.

## CLAIMS

What is claimed is:

1. An intraluminal filter positionable within a lumen for separating entrained particles from a fluid flowing within said lumen, said intraluminal filter comprising a plurality of filamentary members interlaced to form a basket having an upstream portion and a concave portion arranged to face said upstream portion, said upstream portion having openings sized to allow said fluid and said entrained particles to flow through and into said concave portion when said upstream portion is oriented upstream within said lumen, said concave portion comprising a filter element having openings of predetermined size smaller than the first named openings, the openings of said concave portion being sized to capture said entrained particles while allowing said fluid to flow therethrough.

2. An intraluminal filter according to Claim 1, further comprising a means for biasing said basket from a first shape state having a first diameter sized to allow said basket to slidably fit within the bore of a catheter positionable within said lumen, to a biased second shape state having a second diameter substantially larger than said first diameter, said biased second shape state being sized to allow said basket to sealingly interfit within said lumen.

3. An intraluminal filter according to Claim 2, wherein said biasing means comprises selected ones of said filamentary members, said selected ones of said filamentary members being resilient and biased by internal elastic forces to expand said basket into said biased second shape state when said basket is released from said catheter.

4. An intraluminal filter according to Claim 2, wherein said biasing means comprises a plurality of supplemental filamentary members, said supplemental filamentary members being elastic and oriented to compress

said basket into said biased second shape state, said supplemental filamentary members being under tension when said basket is in said first shape state and compressing said basket to bias it into said second shape state upon release of said basket from said catheter.

5. An intraluminal filter according to Claim 4, wherein said filamentary members are interlaced by braiding and said supplemental filamentary members are interbraided with said filamentary members.

6. An intraluminal filter according to Claim 2, wherein said basket comprises a support structure formed of a plurality of first filamentary members and said filter element comprises a plurality of second filamentary members interlaced with one another and said first filamentary members.

7. An intraluminal filter according to Claim 6, wherein at least some of said first filamentary members are resilient and biased by internal elastic forces to expand said basket into said biased second shape state when said basket is released from said catheter.

8. An intraluminal filter according to Claim 6, further comprising a flexible tether attached to said upstream portion of said basket, said tether having a predetermined length and being extendable through said catheter for allowing said filter to be manually withdrawn from said lumen into said catheter bore.

9. An intraluminal filter according to Claim 6, wherein said first and second filamentary members are braided into a tube having a predetermined length, said tube having oppositely arranged ends gathered and cinched to form said upstream and concave portions.

10. An intraluminal filter according to Claim 9, wherein said second filamentary members comprise a thermoplastic polymer.

11. An intraluminal filter according to Claim 10, wherein said second filamentary members are heat fused to said first filamentary members.

12. An intraluminal filter according to Claim 1, further comprising a plurality of projections extending outwardly from said filter and interengaging an internal surface of said lumen for fixing said filter at a predetermined location therein.

13. An intraluminal filter according to Claim 12, wherein said projections comprise a plurality of said filamentary members each having an end extending angularly outwardly from said basket and facing downstream to engage said lumen internal surface.

14. An intraluminal filter according to Claim 13, wherein said projections extend outwardly from said upstream portion.

15. An intraluminal filter according to Claim 2, wherein said biasing means comprises an elongated elastic member having one end attached to said upstream portion and the other end attached to said concave portion, said elastic member being under tension when said basket is in said first shape state and biasing said upstream portion toward said downstream portion to expand said basket from said first to said second shape state.

16. An intraluminal filter according to Claim 15, wherein said elongated elastic member comprises a coil spring.

17. An intraluminal filter according to Claim 1 coaxially mountable on an elongated guide wire, a stopper being positioned on the guide wire at a point along its length, said guide wire being positionable within said lumen, said filter further comprising:

a first aperture located in said upstream portion for receiving said guide wire therethrough;

a second aperture located in said concave portion for receiving said guide wire therethrough;

one of said portions having a surface positioned at one of said apertures to engage said stopper and prevent motion of said filter relative to said guide wire; and

a means for sealing said second aperture.

18. An intraluminal filter according to Claim 17, wherein said surface is positioned at said first aperture.

19. An intraluminal filter according to Claim 17, wherein said sealing means comprises an elongated tube positioned within said basket and coaxially connecting said first and second apertures in sealing relationship, said tube coaxially receiving said guide wire.

20. An intraluminal filter according to Claim 17, wherein said sealing means comprises a check valve positioned in said second aperture, said check valve having a flexible flap movable upon interengagement with said stopper from a closed position sealing said second aperture, to an open position allowing said stopper to pass through said second aperture into said filter.

21. An intraluminal filter for trapping and retaining particles entrained in a fluid flowing within a lumen, said filter comprising:

an elastically deformable basket formed of a plurality of flexible, resilient filamentary members interlaced in a relatively open mesh, the mesh being comprised of openings of a size allowing flow of said fluid and said entrained particles therethrough, said basket being elastically radially compressible to a first shape state having a first predetermined diameter sized to slidably interfit within a catheter positionable within said lumen, and being radially expandable to a second shape state having a second predetermined diameter larger than the first to

sealingly interfit within said lumen, said basket being biased by elastic forces of said filamentary members to nominally assume said second shape state, and being elastically and repeatably deformable between said shape states;

said basket having a relatively open first portion and filter means disposed opposite to said first portion, said filter means having a concave surface of predetermined porosity facing said first portion for capturing said entrained particles when said basket is in said second shape state and positioned in said lumen with said first portion arranged upstream of said filter means.

22. An intraluminal filter according to Claim 21, wherein said filamentary members are monofilament wires.

23. An intraluminal filter according to Claim 22, wherein said filamentary members are interlaced by braiding.

24. An intraluminal filter according to Claim 23, wherein said filter means comprises a multiplicity of multifilament yarns braided with one another and with said filamentary members in a relatively closed mesh.

25. An intraluminal filter according to Claim 22, wherein said filamentary members comprise a radiopaque material.

26. An intraluminal filter according to Claim 25, wherein said radiopaque material is nitinol.

27. An intraluminal filter according to Claim 24, wherein said yarns consist essentially of polyester.

28. An intraluminal filter according to Claim 21, wherein said lumen is a vascular lumen.

29. An intraluminal filter according to Claim 21, wherein the porosity of said filter means ranges between about 60% and 90%.



30. An intraluminal filter according to Claim 21, further comprising a plurality of projecting members having end portions projecting angularly outwardly from said filter and being interengagable with said lumen for preventing downstream movement of the filter, said end portions pointing in the downstream direction to allow said end portions to readily disengage from said lumen when said filter is moved in an upstream direction for retraction of the filter into the catheter.

31. An intraluminal filter according to Claim 30, wherein said projecting members are monofilament wires being selected ones of said resilient filamentary members comprising said basket, said projecting members being present in the ratio of about one to one with said resilient filamentary members.

32. A method of forming an intraluminal filter comprising the steps of:

- providing a plurality of first filamentary members, said first filamentary members being flexible and resilient;
- braiding said plurality of first filamentary members into a relatively open mesh forming an elastically deformable tube;

- interbraiding a plurality of second filamentary members with said first filamentary members to form a surface having a predetermined porosity;

- biasing said first filamentary members to urge said tube to assume a predetermined length and diameter;

- gathering each end of said tube and cinching each said end together to form an elastically deformable basket;

- removing said second filamentary members from a portion of said basket at one end of said tube thereby forming openings at said one end; and

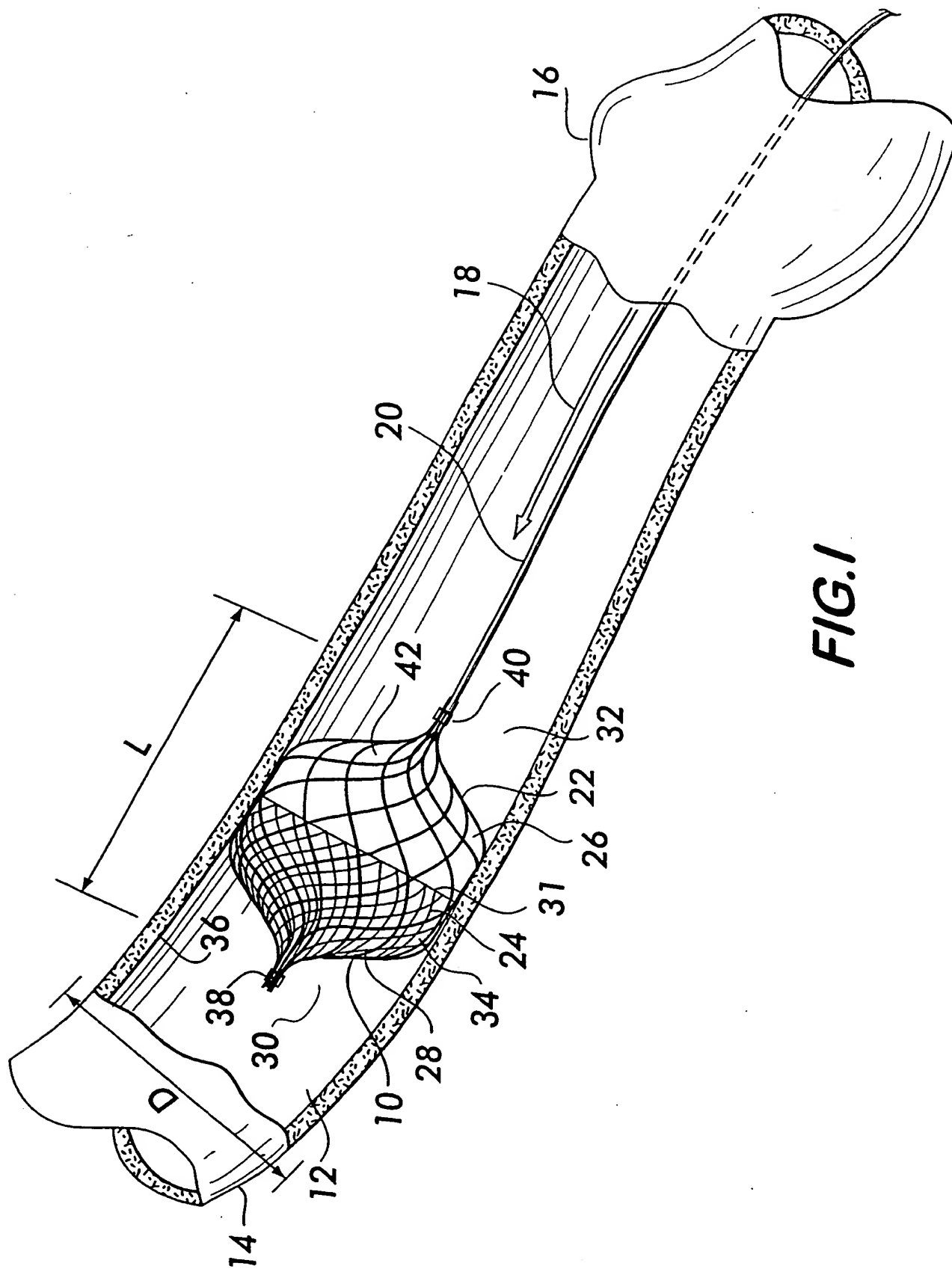
- attaching said second filamentary members to said first filamentary members adjacent to said portion of said basket.

33. A method of forming an intraluminal filter according to Claim 32, wherein said second filamentary are

formed of a polymer, said polymer having a lower melting point than said first filamentary members and said removing step is performed by ablating said second filamentary members.

34. A method of forming an intraluminal filter according to Claim 33, wherein said attaching step is performed by heat sealing said second filamentary members to said first filamentary members.

1/8



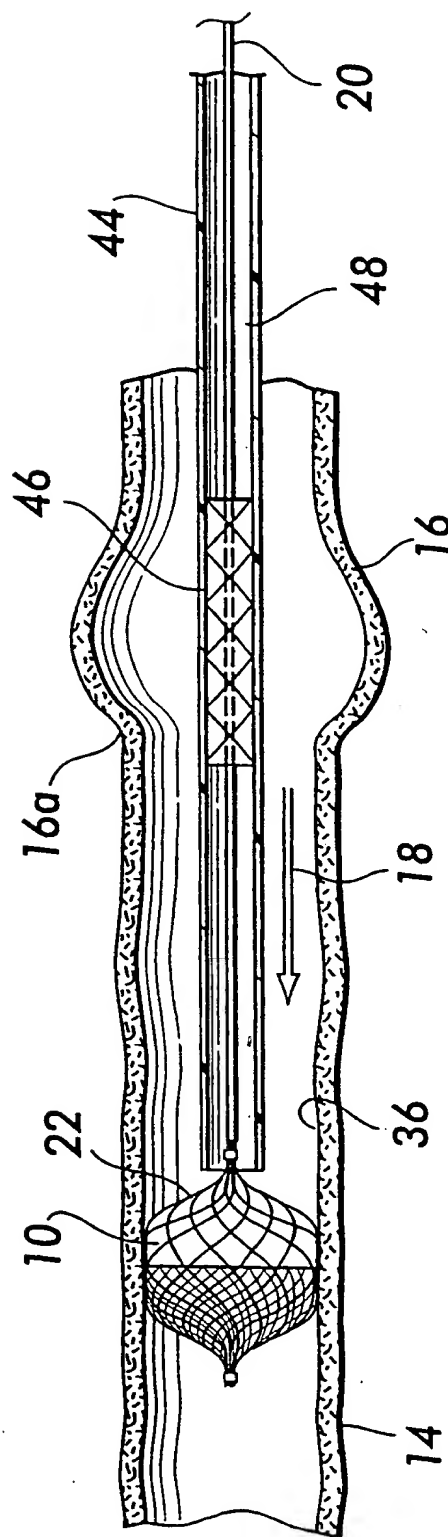
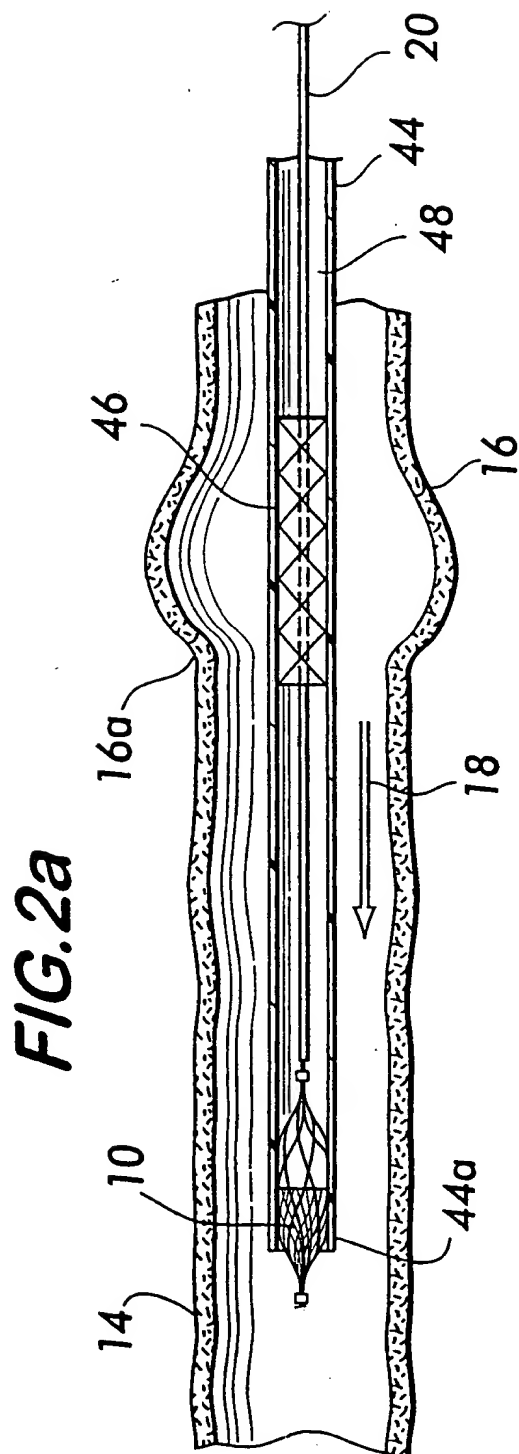


FIG. 2c

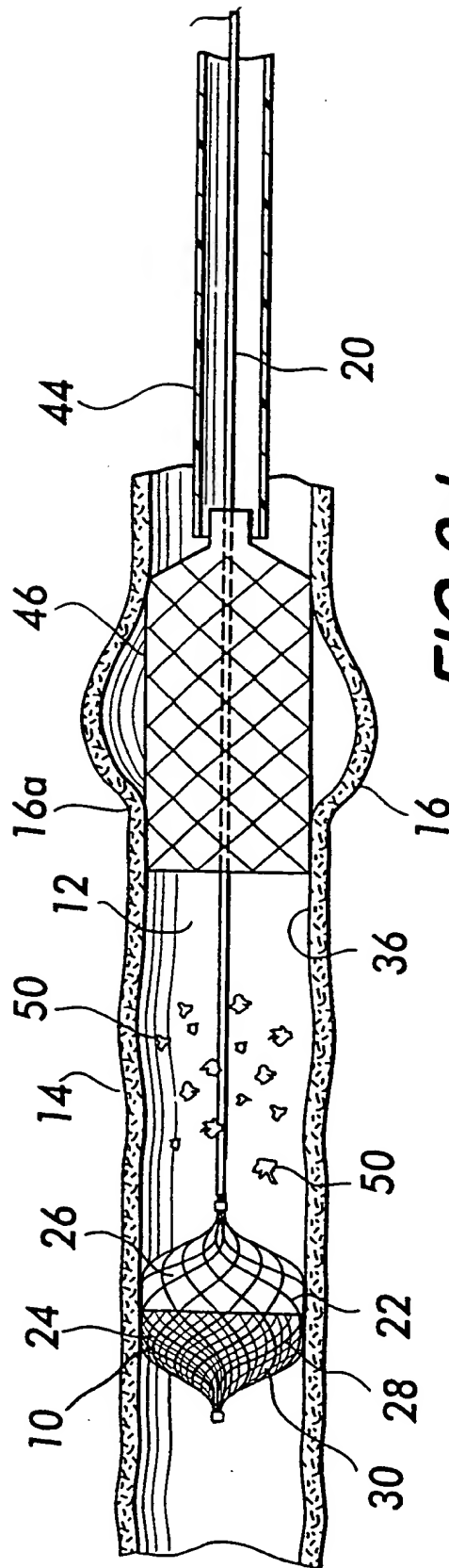
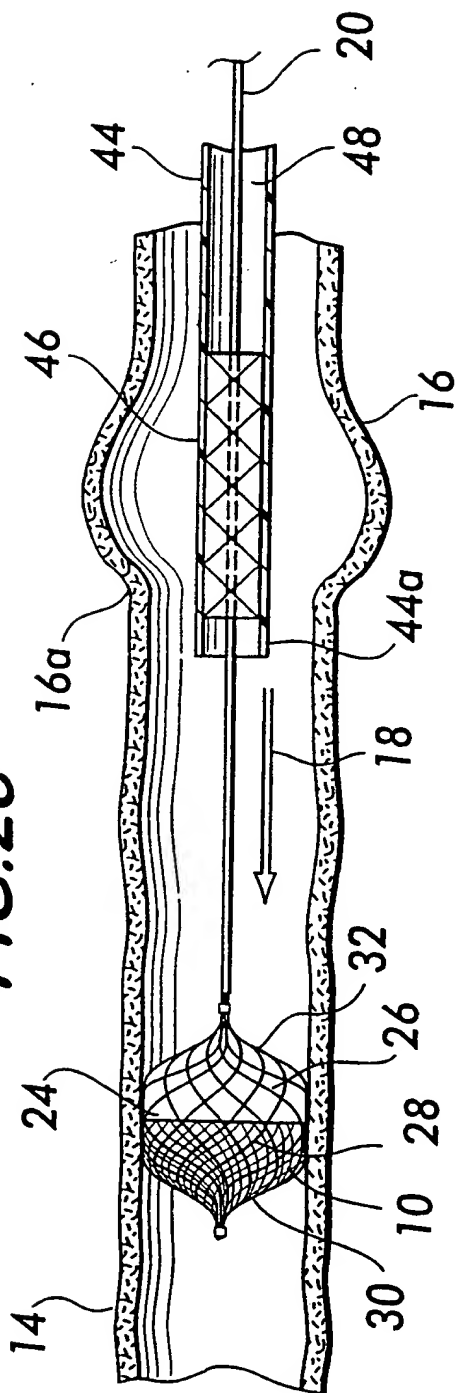


FIG. 2d

FIG. 2e

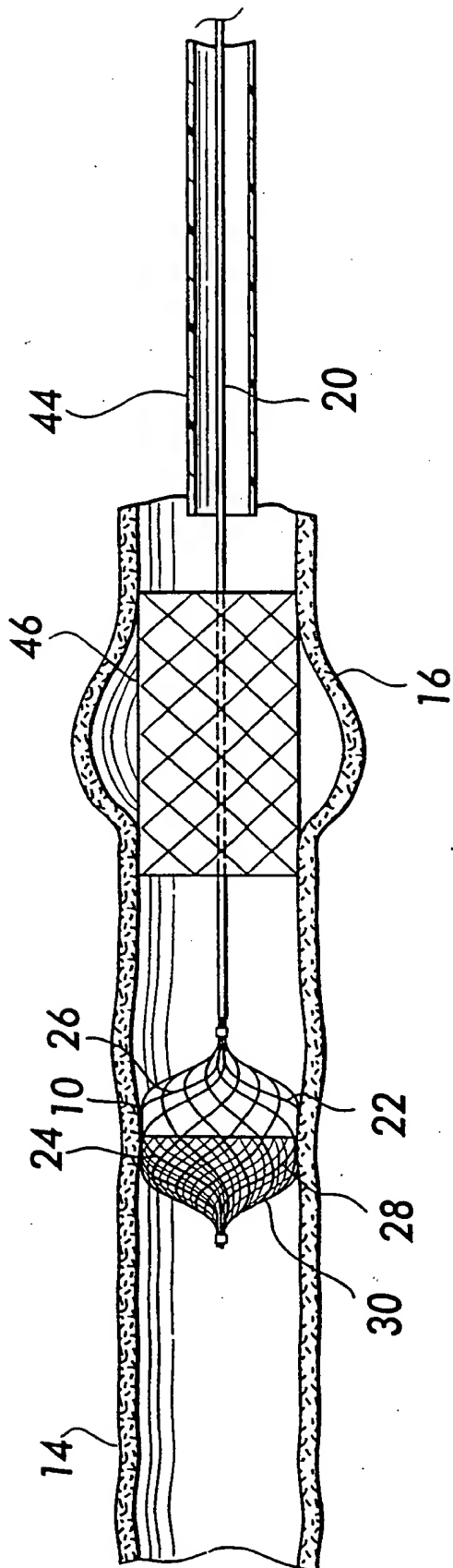
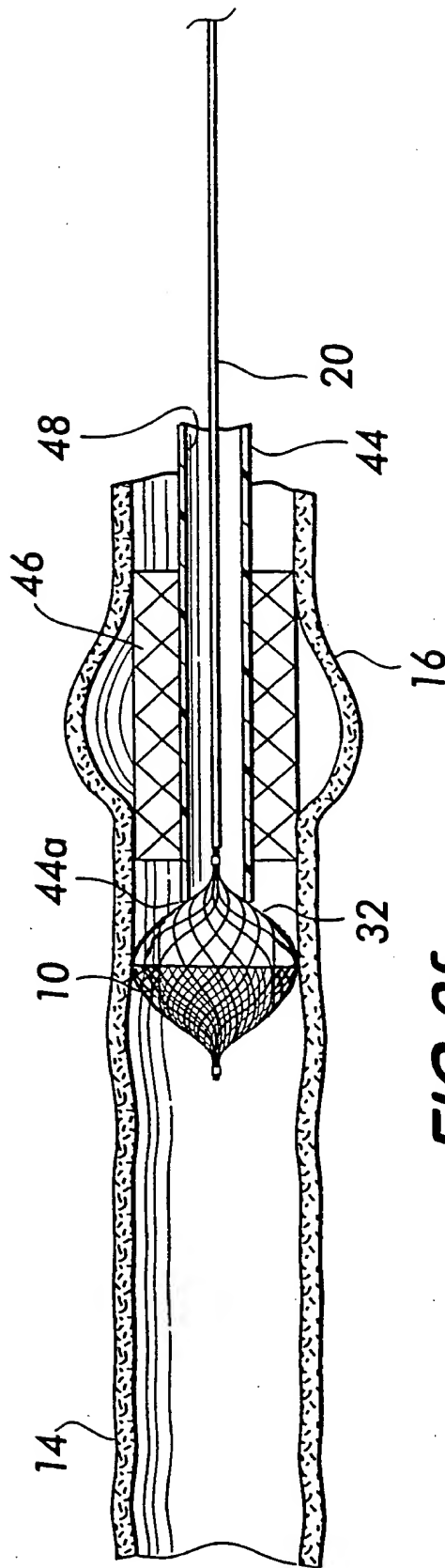


FIG. 2f



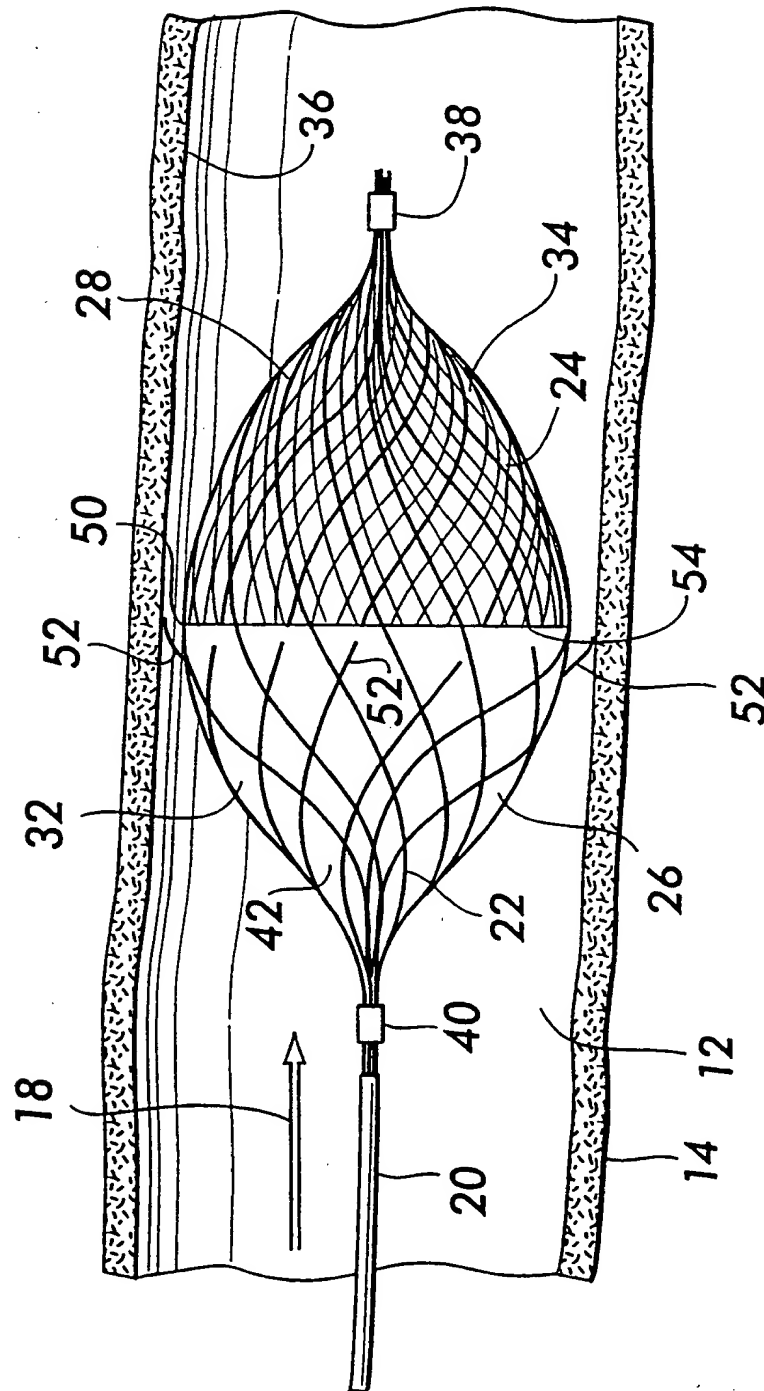
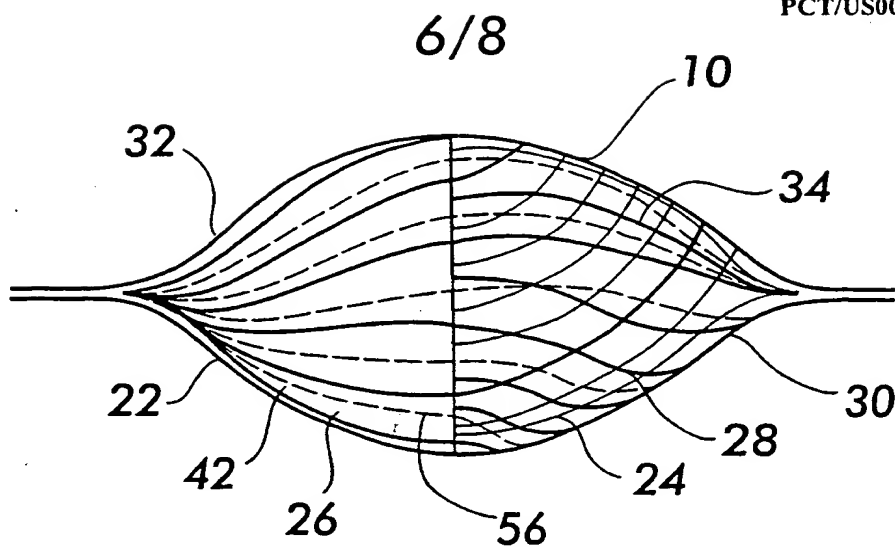
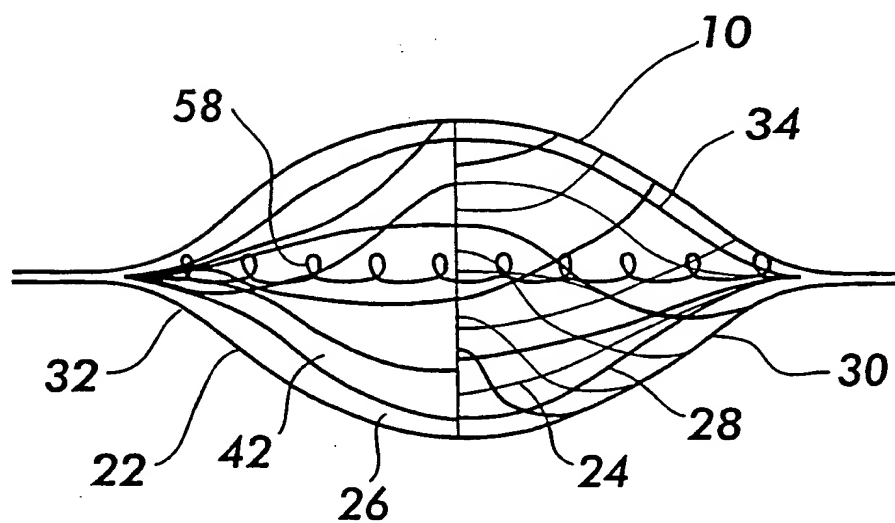


FIG. 3

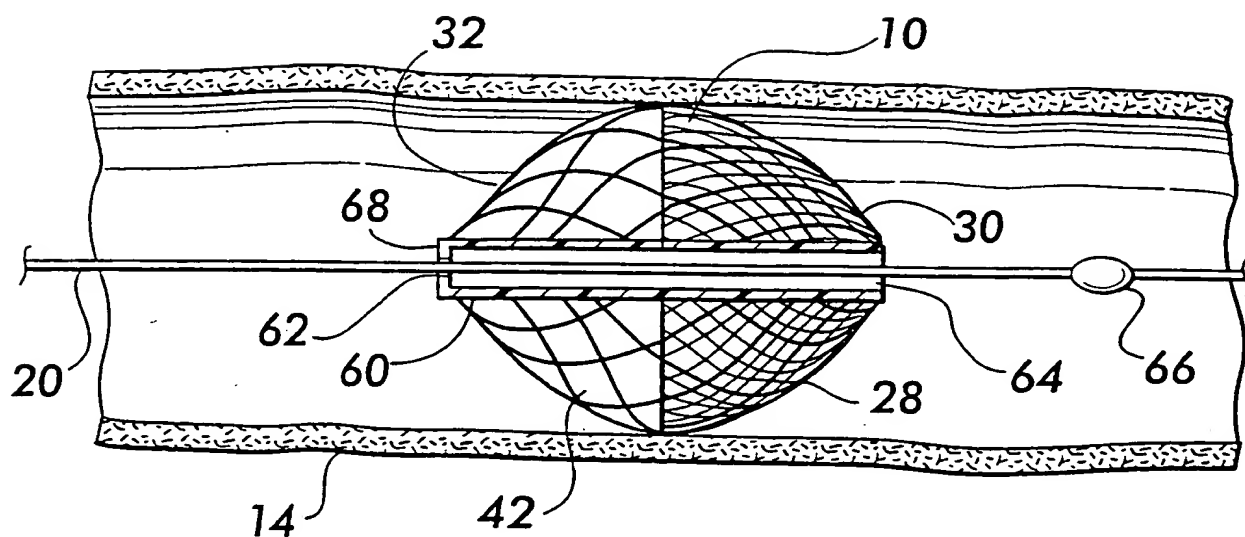
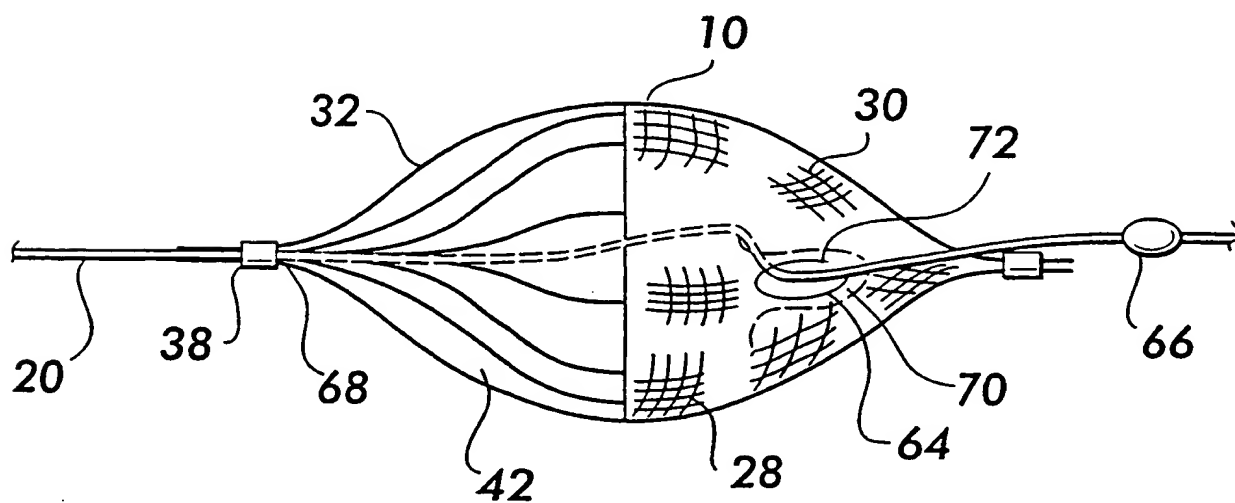


**FIG. 4**

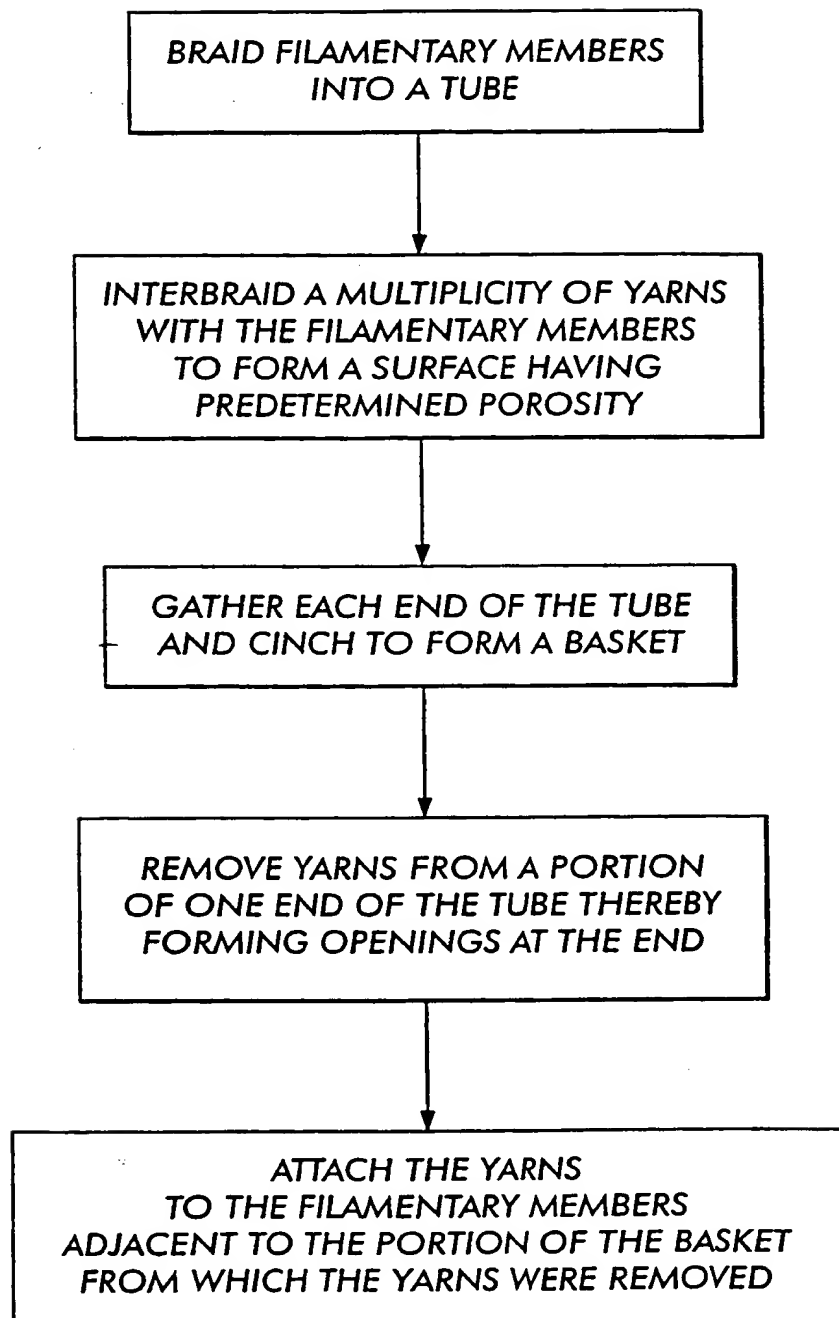


**FIG. 5**



**FIG. 6****FIG. 7**

8/8

**FIG. 8**

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/24572**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61M 29/00

US CL :606/200

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96; 606/158, 159, 192, 200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,814,064 A (DANIEL et al.) 29 September 1998, Figs.13, 14 ,and 19.	1-34
X,P	US 6,059,814 A (LADD) 09 May 2000, Fig.1.	1-15, 21-24
X	US 5,379,331 A (HIMPENS et al.) 14 March 1995, Fig. 10.	1, 2, 17-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

13 OCTOBER 2000

Date of mailing of the international search report

12 DEC 2000

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

LIEN NGO

Telephone No. (703) 305-0294